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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,134	10/31/2000	Andrey A. Boukharov	04983.0201.00US00/38-21(5	8935

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/702,134	BOUKHAROV ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 21 May 2003.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-4 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>0901</u> .	6) <input checked="" type="checkbox"/> Other: <u>Sequence search results</u> .

DETAILED ACTION

1. The Sequence Listing filed October 31, 2000 has been entered.

Election/Restriction

2. It is first noted that, in accordance with Applicant's instructions in the Letter of May 21, 2003, the Response filed May 5, 2003 has been considered, and the Response filed May 2, 2003 has been disregarded.

3. Applicant's election with traverse of Group I, claims 1-4, and of SEQ ID NO: 7212, in the Response filed May 5, 2003 is acknowledged. The traversal is on the following ground(s). The response argues that the examiner has not established that search and examination of the entire application would pose a serious burden. The response further argues that Groups I and II "should be examined simultaneously because they are related as nucleic acid molecules." The response also states that "Applicants believe no serious burden would result by the search and examination of at least 10 nucleotide sequences."

Applicant's arguments have been thoroughly considered but are not found persuasive for the following reasons. First, with regard to the separation of Groups I and II, while it is acknowledged that all nucleic acids are composed of common building blocks (specifically, nucleotides), it is again noted that the molecules of Group I and Group II differ both in structure (i.e., in nucleic acid sequence) and in functional properties, and as such require different searches. The molecules of Invention II encode particular proteins and therefore require both text and sequence searches of those specific proteins and the nucleic acids encoding them, while the molecules of

Art Unit: 1634

Invention I are genomic fragments that require searches of different nucleic acid structures that comprise coding and non-coding sequences. Similarly, each particular sequence encompassed by both Group I and Group II has a different structure and different functional characteristics, and requires a separate search differing from that required for each other sequence. The fact that the different Groups and each of the sequences encompassed thereby would require a different search is sufficient to establish that the examination of more than one Group and more than one such sequence would pose a serious burden (see MPEP 803). Further, it is noted that a search of the single elected 70 kb sequence required multiple days of computer processing time (to accomplish the sequence portion of the search alone); a search of 10 such sequences would require multiple weeks, and a search of all of the claimed sequences would require multiple years. Accordingly, applicant's arguments are not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 5-7, and all sequences other than SEQ ID NO: 7212 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Response of May 5, 2003.

Specification

5. The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

6. The use of the trademarks GENBANK®, TAQMAN®, and HYBOND™ has been noted in this application. The trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

7. The title of the invention is not descriptive of the elected subject matter (which is a nucleic acid molecule, but not a use thereof). A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

9. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The claimed subject matter is not supported by a specific, substantial, and credible asserted utility because the disclosed uses are generally applicable to broad classes of this subject matter. Further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification teaches that SEQ ID NO 7212 is one of a group of over 50,000 large genomic fragments obtained from rice (see entire specification). The specification asserts that a variety of uses are applicable to all of the disclosed sequences, including use of the various sequences in genomic mapping, gene identification and analysis, plant breeding, preparation of expression constructs, preparation of transgenic plants, screening for traits, and determination of polymorphisms and of associations between polymorphisms and traits (see entire specification, particularly, e.g., pages 1, 12, and 18). However, the uses asserted in the specification are general utilities and methods of further research that are applicable to virtually any genomic nucleic acid from any plant. For example, any plant nucleic acid could be employed in genomic mapping, and any plant nucleic acid could be analyzed from the presence of genes (which genes

could further be subjected to analysis); such general methods do not constitute substantial uses that are specific to one or more of the molecules disclosed by applicant. Further, while such mapping and nucleic acid analysis might eventually result in the identification of, e.g., particular regulatory elements useful in recombinant expression methods or in preparation of transgenic plants, specific polymorphisms associated with specific traits, particular open reading frames encoding useful proteins, etc., such further research and experimentation on nucleic acids also constitutes a general utility, rather than a specific and substantial "real world" use. See *Brenner v. Manson*, 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". A patent is therefore not a license to experiment with the objective of eventually identifying a specific and substantial use for a product or method. With regard to SEQ ID NO: 7212 in particular, while the specification discloses that the sequence has been examined for homologies with known genes (see, e.g., Table 1), the specification does not provide any evidence that applicants have, e.g., identified within SEQ ID NO: 7212 any particular polymorphisms associated with a trait or traits, identified any particular promoters or regulatory elements useful in methods of recombinant gene expression, determined that any of the putative open reading frames in the sequence actually encodes a protein having a specific use, etc. Accordingly, the claimed invention is not supported by a specific, substantial and credible asserted utility.

With regard to the possibility that there may exist a well-established utility for the claimed invention, it is noted that SEQ ID NO: 7212 is free of the prior art. A search of

Art Unit: 1634

the prior art indicates that SEQ ID NO: 7212 does contain a region of significant homology with a known molecule, specifically, with a rice cDNA encoding gibberellin 20-oxidase (GENBANK Accession No. U50333, February, 1997). However, an alignment of this cDNA with SEQ ID NO: 7212 reveals (in addition to multiple mismatches) multiple frameshifts within the coding sequence of the cDNA; accordingly, the prior art indicates that SEQ ID NO: 7212 and the prior art cDNA do not in fact encode the same protein. Thus, the prior art does not provide any evidence of a well-established utility for SEQ ID NO: 7212.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

12. Sequence search results are cited to show the sequence identity shared between a portion of instant SEQ ID NO: 7212 and GENBANK Accession no. U50333.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in dark ink, appearing to read "Diana B. Johannsen", followed by a long, sweeping horizontal line that extends across the page.

Diana B. Johannsen
August 8, 2003